PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DVP-0103	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/MX 03/00027	International filing date *(day/month/year)* 14.03.2003	Priority date *(day/month/year)* 14.03.2003
International Patent Classification (IPC) or both national classification and IPC A61F2/46		
Applicant FERREYRO IRIGOYEN, ROQUE HUMBERTO		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.10.2004	08.04.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Schmierer, U Telephone No. +49 89 2399-2603

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/MX 03/00027

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-17 filed with the demand

Claims, Numbers

1-5 received on 16.03.2005 with letter of 16.03.2005

Drawings, Sheets

1/7-7/7 filed with the demand

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 5

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 5

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-4
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-4
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-4
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Independent method claim 5 corresponds to independent method claim 6 as filed with the demand. Last said claim, however, was not searched.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

(1) The invention refers to syringes for injection of bone cement.

(2) The problem is to avoid the disadvantages occurring in prior art devices, such as mechanical deformation by high injection forces of insulin syringes used for said purpose, the need for syringe exchange, exposition of the surgeon's hand to radiation.

(3) The prior art according to D1 (EP-A-235 905) is a system for remote actuation of an insulin syringe comprising an injection syringe, a pressure exerting body, a hydraulic transmission tube and an manual impulsion and fluid transmission syringe.

(4) The solution according to the claims is an injection syringe in the form of a commercially available 3 ml hypodermic syringe, a hydraulic tube of 1.0 to 1.5 m length for pressure transmission and a pressure exerting body having a diameter larger than the diameter of the manual impulsion and fluid transmission syringe.

(5) Provision of said features involves inventive step, since the prior art system is for remote insulin injection for patients suffering from diabetic neuropathy. There is no hint towards adaption of said system to the purpose of cement injection by provision of a 3 ml hypodermic syringe, since injection of insulin according to D1 must be done with an insulin syringe. Further, from D1, it is not made obvious to provide a hydraulic tube for pressure transmission, the tube having a length of 1.0 to 1.5 m, since the purpose of the tube according to D1 is to help in avoiding shifting of the needle by a trembling hand. Finally, in the device according to D1, there is no need for the particular relationship of the diameters, since the injection force for insulin is low.

(5.1) According to WO-A-9728835, there is provided a system for injection of minor amounts of medicine, in which system the injection syringe is of less size than the actuation syringe. Further, pressure in said system is limited.

CLAIMS

1.- Hydraulic device for injection of bone cement in percutaneous vertebroplasty, that comprise four main parts, namely: injecting syringe, pressure exerting body, hydraulic transmission tube, an manual impulsion and fluid control syringe; the injection syringe is a commercially available disposable 3 ml hypodermic syringe placed next to the patient; the hydraulic tube for pressure transmission, of 1.0 m to 1.5 m length, placed between the injection syringe and the pressure exerting body; the manual impulsion syringe placed after the hydraulic tube and near the operator, characterized by the pressure exerting body consist of hollow cylindrical body in the form of inverted syringe of larger diameter with an adapted ending like an open bolster with the largest external diameter and two diametrical opposed cuts like oval entry, also in the other end one tip of reduced diameter; an peripheral groove in the internal wall of such bolster, couples tightly the wings of injection syringe in a revolved way; such pressure exerting body has a movable piston on axial direction to define two chambers, namely, internal and external.

2.- Hydraulic device of injection of bone cement according to the claim 1, characterized by the cylindrical hollow of pressure exerting body (1), in form of an inverted positioned syringe that renders mechanical advantage to the force exercised in the manual syringe, it has a larger diameter and consists of a joining bolster with internal peripheral groove where are coupled the wings of injecting 3 ml syringe; a body cylindrical lengthened hole of 10 ml of volume that contains a first free camera where the plunger (c) of the injection syringe lodge inside the cylinder until coupled with the moving internal piston (4), and a second internal

camera (5) occupied by a hydraulic fluid, this cameras are separated by such piston (4) surrounded by a rubber cap that seals the internal wall of the body of pressure and avoids leakage of the hydraulic fluid; a final end tip of reduced diameter that is connected in a hermetic way to the hydraulic tube (7).

3.- Hydraulic device of injection of bone cement according to the claim 2, characterized by the bolster is adapted to receive in a first predetermined position of an oval entry (70) the wings of the injection syringe, and in second position by a 90° turn in a peripheral groove (90), placed in a tight way.

4.- Hydraulic device of injection of bone cement according to the claim 1, characterized by the manual syringe (8) is a lengthened syringe that has a smaller diameter than the pressure exerting body in a 2/1, 3/1, 4/1 ratio, it is connected in continuation, far from the application point by a hydraulic tube.

5.- A method of operating the device for injection of bone cement that comprises:

to insert a bone biopsy needle in the place where the bone cement is to be delivered.

to connect the injecting syringe, loaded with the cement, in continuation of the needle;

to couple in a revolved way, the injecting syringe in the internal peripheral groove of the bolster of the pressure exerting body;

to exert pressure on the plunger of the injecting syringe by means of the force exerted in the plunger of the manual syringe placed in the other end of the

hydraulic tube, this way, the content of the injecting syringe is injected in the patient's vertebral body;

to retract the plunger of the manual syringe to withdraw the internal piston of the body of pressure in position to receive a new loaded cartridge of bone cement;

to uncouple the injecting syringe from the bolster of the body of pressure;

to disconnect the empty syringe from the needle placed in the patient's body;

to couple the new cartridge of bone cement (injecting syringe) in the needle and bolster of the body of pressure, and repeat the previous steps to place another new cartridge of bone cement, until completing the filling of the vertebral body.